



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 2004

AB Ardent
C/O Mr. Clyde E. Ingersoll
Official Correspondent & Agent
Ardent Product Development
54 Riverview Avenue
Tonawanda, New York 14150-5260

Re: K040465
Trade/Device Name: Latit Flow
Regulation Number: 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: May 18, 2004
Received: May 21, 2004

Dear Mr. Ingersoll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT #4
Indications for Use

510(k) Number:

K040465

Device Name: LATIT FLOW

Indications for Use

LATIT FLOW is to be used as a filling material for restoring function to teeth that have lost portions due to caries:

Direct, fixed restorations, placed by the dentist after removal of carious tissue.
Anterior restorations, Class III, IV
Class V restorations, cervical caries, root erosion, wedge shaped defects.
Small posterior restorations, Class I,
Mini cavities, minimal invasion dentistry
Veneering of discolored anterior teeth
Splinting of mobile teeth.
Preventive restorations in molars and premolars.
Repair of composite and ceramic veneers.
Luting of porcelain and composite veneers
As first layer of Class I or II restorations

Contra indications:

The placement of LATIT FLOW is contraindicated

If a dry working field cannot be established or if the stipulated technique cannot be applied.

If the patient is known to be allergic to the components of LATIT FLOW.

Prescription Use X
(Part 21 CFR801 Subpart D)

AND/OR

Over-the-counter Use _____
(Part 21 CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Pinner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: _____

K040465

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